K091115

OCT 3 0 2009

510(k) Summary for the
Lutronic Corporation eCO2 Laser System

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	Lutronic Corporation #403-2,3,4, Ilsan Technotown 1141-1 Baeksok-Dong, Ilsan-Gu Goyang-Si, Gyeonggi-Do, 410-722 Republic of Korea
Contact Person:	Maureen O'Connell O'Connell Regulatory Consultants, Inc. 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-824-2541
Summary Preparation Date:	October 26, 2009

2. **Names**

Device Name:	eCO2 Laser System
Classification Name:	Laser Instrument, Surgical, Powered Product Code: GEX Panel: General & Plastic Surgery

3. **Predicate Devices**

The eCO2 is a modification of the eCO2 cleared in K080496. The indications for use are exactly the same as the cleared eCO2. Additionally, the eCO2 is substantially equivalent to the the Reliant Technologies, Inc. Fraxel III SR Laser System (Fraxel re:pair) and Accessories (K080915); the Lasering SLIM Evolution Family of CO2 Lasers with Mixto SX Scanner (K063001); Lumenis, Inc. Active FX and Deep FX UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Device Accessories (K022060 and K030147); and the Cynosure, Inc. Smart CO2 (K031224).

4. Device Description

The eCO2 Laser System consists of a self-contained console, an articulated arm delivery system with scanner handpiece and a footswitch. The eCO2 produces a beam of coherent infrared light (10.6um) and has two operation modes (Static mode and Dynamic Mode). The laser works in medical applications because 10.6um is near the peak of tissue water absorption. When the water in the tissue absorbs the laser energy, it heats up. This heating causes instantaneous vaporization of the target tissue.

The eCO2 Laser System utilizes a CO_2 RF module to generate a laser beam with a wavelength of 10.6 um and uses a scanner handpiece. The physician can optimize the effect for different applications by controlling the power of the laser pulse and using a different scan pattern.

5. Indications for Use

The eCO2 Laser System is indicated for use in dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue. Additionally, the 120 micron and 300 micron spot sizes are used in the treatment of wrinkles; rhytides, furrows, fine lines, textural irregularities, pigmented lesions and vascular dyschromia.

6. Performance Data

None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Lutronic Corporation
% O'Connell Regulatory Consultants, Inc.
Ms. Maureen O'Connell
5 Timber Lane
North Reading, Massachusetts 01864

OCT 3 0 2009

Re: K091115
Trade/Device Name: eCO2 Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 30, 2009
Received: October 1, 2009

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 091115

Device Name: eCO2 Laser System

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Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091115